

Home-Use Medical Devices: Human Factors

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Home-Use Medical Devices: Human Factors

The User

- Patients and Lay Caregivers:
 - Varied needs of the user
 - Written information
 - Professional Instruction
 - Design regulations for devices (21 CFR 820.30)

Home-Use Medical Devices: Human Factors

- Varied Needs
- Device information they:
 - Need
 - Want
 - Don't want

Home-Use Medical Devices: Human Factors

- Adequacy of information
 - Instructions for use
 - Risk Benefit information
 - Conditions of use

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- Written information format:
 - Table of Contents
 - Descriptive Information
 - Name / specific identifiers
 - Purpose
 - Description of the device and its purpose
 - Risk/benefit information
 - Expectations
 - Warnings and Precautions

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- Written information format (cont.)
 - Operations Information
 - Set up
 - Maintenance/storage
 - Device specific topics
 - Troubleshooting

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- Written information format (cont.)
 - Additional Information
 - Scientific Information
 - Self care, disease information
 - Listing of adverse events
 - Outcome rates (results)
 - Travel / international use
 - "Help" telephone numbers

Home-Use Medical Devices: Human Factors

FDA's Home Healthcare: Checklist for Users

www.fda.gov/cdrh/CDRHHHC/brochure-checklist.html

Home-Use Medical Devices

Additional FDA Information:

<http://www.fda.gov/cdrh/cdrhhhc/>

Resource Information:

<http://www.nfcacares.org>